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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,489	01/23/2001	Lisa Joanne Drewe	41577/252464	5644

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 11/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/744,489	DREWE ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,6,8-12,14,16 and 18-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6,8-12,14,16 and 18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 01, 2005 has been entered.

Status of the Application

2. The action is in response to the RCE filed on September 01, 2005. Currently claims 1-2, 5-6, 8-12, 14, 16, 18-24 are pending. Claims 3-4, 7, 13, 15, 17 are cancelled. All arguments and amendment have been fully considered and thoroughly reviewed and deemed persuasive in view of the amendment.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

A. Claims 1, 5-6, 8-12, 14, 16, 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vary et al. (USPN. 5,800,984) in view of Kai et al. (Nucleic acids symposium series No. 37, page 321-322, 1997).

Vary et al. teach a method of claims 1, 6, 18, 21, for detecting the presence or absence of a target nucleic acid sequence in a sample comprising

(a) amplifying said target nucleic acid and introducing a purine rich region into the target sequence during amplification, wherein the resulting target is able to bind to a complementary triplex forming probe (see col. 5, line 43-55, col. 6, line 45-67, col. 8, line 7-49, col. 9, line 45-54, indicating purine rich region is introduced into PCR product during amplification reaction, wherein it is capable of hybridizing with a complementary triplex forming probe);

(b) detecting the presence of triplex structures resulting from the hybridization of target sequence with the probe, wherein the detection of the presence of the triples structures indicates the presence of the target nucleic acid sequence in the sample (see col. 58-64, col. 8, line 50-56, col. 9, line 54-63).

With regard to claim 5, 22, Vary et al. teach that the amplification reaction is a polymerase chain reaction col. 5, line 43-58, col. 8, line 7-10);

With regard to claim 8, Vary teach that the PCR primers comprise plurality of pyrimidines at the 5' end (see col. 6, line 60 indicating the triplex primer comprising plurality of pyrimidines);

With regard to claim 9, 23, Vary et al. teach that the probe is immobilized to a solid support (see col. 5, line 63-67, col. 6, line 1-14);

With regard to claim 12, 24, Vary et al. teach the triplex structure is detected by a gel retardation method (see col. 9, line 54-67);

With regard to claims 14, 16, Vary et al. teach a kit comprising triplex forming probes attached to a solid support and primers (see col. 3, line 49-65).

However, Vary did not specifically teach peptide nucleic acid probe to form triplex structure and detection of the triplex using wave guide detection device.

Kai et al. teach a method for specific-specific DNA detection using distinctive properties of a novel system employing peptide nucleic acid probes, wherein Kai et al. disclose hybridizing PNA probe with PCR amplification products simultaneously in a PCR reaction (real-time PCR) and monitoring the change in resonance units to detect the hybridization complex (triplex structure) suing Surface Plasmon Resonance detector device (see page 321, col. 1, abstract, col. 2, paragraph 3 under results and discussion).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of detecting the presence of a target nucleic acid sequence in a sample as taught by Vary et al. with a step of including a PNA probe to form triplex structure with the PCR amplified products and detecting the triplex using a waveguide detector (SPR) as taught by Kai et al. for the purpose of improving the sensitivity and specificity of the detection method. One skilled in the art would be motivated to combine the method as taught by Vary et al. with the inclusion PNA probe and as taught by Kai et al. because Kai et al. explicitly taught that the use peptide nucleic acid probes in detecting and a combination of PNA

and SPR provide a sensitive detection and monitoring of sequence-specific target nucleic acid (see page 321, col. abstract, page 322, col. 1, line 10-14). The ordinary artisan would have a reasonable expectation of success that inclusion of PNA probe would result in detecting sequence-specific target nucleic acids that minimizes false positives as suggested by Kai et al. and such modification of the method would be obvious over the cited prior art in the absence of secondary considerations.

B. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vary et al. (USPN. 5,800,984) in view of Kai et al. (Nucleic acids symposium series No. 37, page 321-322, 1997) as applied to claims 1, 5-6, 8-12, 14, 16, 18-24 above, and further in view of Armitage et al. (Nucleic Acids Res., Vol. 25, No. 22, page 4674-4678, 1997).

Vary et al. in view of Kai et al. teach a method for detecting the presence of a target nucleic acid as discussed in the section 3A above.

However neither Vary et al. nor Kai et al. taught that the peptide nucleotide probe (PNA) as a bis-PNA.

Armitage et al. teach a method for detecting strand invasion and mapping the secondary and tertiary structures of nucleic acids uisng bis-peptide nucleic acid conjugates, wherein Armitage et al. teach that the use of bis-PNA stabilizes PNA-DNA complexes and exhibit high degree of sequence selectivity during strand invasion complex formation (see page 4674, col. 2, paragraph 1, page 4676, col. 1, paragraph 1).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of detecting the presence of a target nucleic acid sequence in a sample as taught by Vary et al. in view of Kai et al. with a step of including a bis-

PNA probe to form a stable hybridization complex as taught by Armitage et al. for the purpose of improving the stability and specificity of the hybridization complex. One skilled in the art would be motivated to combine the method as taught by Vary et al. in view of Kai et al. with the inclusion bis-PNA probe and as taught by Armitage et al. because Armitage et al. teach that the use of bis-PNA stabilizes PNA-DNA complexes and exhibit high degree of sequence selectivity during strand invasion complex formation (see page 4674, col. 2, paragraph 1, page 4676, col. 1, paragraph 1). The ordinary artisan would have a reasonable expectation of success that inclusion of bis-PNA probe would result in enhancing the stability of sequence-specific hybridization complex and detection of stable hybrids that minimizes non-specific hybridization and such modification of the method would be obvious over the cited prior art in the absence of secondary considerations.

Response to arguments:

4. With regard to the rejection maintained in the previous office action under 35 USC 102(b) as anticipated by Seeger et al., Applicants' arguments and amendment are fully considered and the rejection is moot in view of the amendment and new grounds of rejections.

5. With regard to the rejection maintained in the previous office action under 35 USC 103(a) as being obvious over Seeger et al. in view of Felger, Applicants' arguments and amendment are fully considered and the rejection is moot in view of the amendment and new grounds of rejections.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prabha Chunduru

Suryaprabha Chunduru
Patent Examiner
Art Unit 1637

11/14/05